

Reply under 37 CFR 1.116 – Expedited Procedure - Technology Center 3736
Application No. 09/863,234 Art Unit 3736
Docket No. 0101-P00636US4 Examiner: Lacyk, J.

REMARKS

Claims 9-14, 16-19, 23-30, 32-50, 52-56, 84-132 are pending in the application, claims 15, 20-22, 31, 51, and 57-83 having been canceled above. Claims 84-132 have been newly presented above to claim additional aspects of Applicants' invention.

OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 9-83 were rejected under the “judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of U.S. Patent No. 5,645,081...” Claims 9-83 were also rejected under the “judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of U.S. Patent No. 5,636,643...” In response, two terminal disclaimers are enclosed herewith. Accordingly, Applicants understand that the double patenting rejections are overcome and respectfully request withdrawal of such rejections.

REJECTIONS UNDER 35 U.S.C. 112

Claims 9-13 and 23 stand rejected under 35 U.S.C. 112 first paragraph, “as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims now claim a ‘seamless’ cover or a ‘seamless’ seal...” Applicants have amended independent claims 9, 13, and 23 to delete the respective terms “seamless cover” and “seamless seal”. Claim 9 now recites “a one-piece cover”; claim 13 recites a “continuous, uninterrupted seal”; and, claim 23 recites a “one-piece flexible sheet”. Support for the quoted claim language may be found in the application in at least Fig. 1 and the associated text. Accordingly, Applicants understand that the rejections of claims 1-13 and 23 under 35 U.S.C. 112 first paragraph to be overcome and respectfully request that such rejections be withdrawn.

Claims 37, 51, and 72 were rejected under 35 U.S.C. 112, second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims appear to be incomplete... in that the dome, cover

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or chamber needs to be positively claimed in order to have a working device...” Claims 51 and 72 have been canceled above rendering their rejection moot. Claim 37 has been amended to recite a cover. Accordingly, Applicants understand that the rejections of claims 37, 51, and 72 are overcome and respectfully request that such rejections be withdrawn.

REJECTIONS UNDER 35 U.S.C. 102

Claims 9-14, 19, 23-26, 30-33, 37-41, 51, 52, 57-63, 72-75, and 83 were rejected under 35 U.S.C. 102(b) as being anticipated by Zamierowski. The office action states that “Zamierowski discloses a device for treating wounds having a cover, a means for providing a reduced pressure or suction and a screen between the cover and the wound. Zamierowski also teaches using a collection device for collecting what is drawn out by the device.” Applicants respectfully note that more than one patent to Zamierowski is of record in the instant case; however, the office action does not indicate which Zamierowski is being applied. In the interest in advancing the prosecution of this application, Applicants are responding to the rejections under the assumption that US 4,969,880 is the Zamierowski patent being applied in the instant office action. Applicants respectfully request confirmation that US 4,969,880 is the reference being applied in the instant office action.

Applicants’ claimed invention relates to a device and method for healing wounds by applying reduced pressure at the site of a wound to promote the formation of healthy tissue, such as granulation tissue. In contrast, Zamierowski discloses a simple drainage device for “the evacuation of drained fluids” and “the introduction of liquid medications.” Zamierowski, column 2, lines 13-16. For example, creating a reduced pressure environment about the wound is not recited as one of the objects of Zamierowski as listed at column 2, lines 12- 25. In this regard, the device disclosed by Zamierowski is not configured to create or maintain a reduced pressure environment about the wound. Indeed, the disclosure of Zamierowski provides at least three separate indications that reduced pressure is not created within the device of Zamierowski.

First, the membrane of Zamierowski is not sealed relative to atmospheric pressure. The relevant text of Zamierowski states that:

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The membrane perimeter 26 is pressed against the healthy skin 16 surrounding the wound site 12 to preferably form a relatively liquid-tight adhesive bond therebetween. (underlining added)(Zamierowski, column 4, lines 65-68).

A relatively liquid-tight bond as disclosed in Zamierowski is not an air-tight bond of the type needed to maintain reduced pressure at a wound site. While a relatively liquid-tight bond may be sufficient to retain some degree of liquid, it is not suited for maintaining reduced pressure at a wound site and is not Applicants' claimed "liquid impermeable seal" as recited in independent claims 33, 37, and 52 or Applicants' claimed "liquid impervious seal" as recited in dependent claims 105 and 106. Further, the above-quoted text of Zamierowski, reciting a relatively liquid-tight adhesive bond, must be considered in view of the figures of Zamierowski, which show air gaps at the perimeter – a second indication that reduced pressure is not created within the device of Zamierowski.

The figures of Zamierowski clearly show that the wound chamber 46 is not designed to be sealed with respect to atmospheric pressure. More specifically, Figures 1, 2, and 6 of Zamierowski show that the chamber 46 communicates with atmosphere through triangular air gaps formed between the two upturned edges 20 of the seam 21 of the "pair of panels 19" of the Zamierowski cover membrane 22. (See Exhibit A.) This triangular air gap is clearly illustrated in the side cross-sectional views of Figures 2 and 6 and in the side cross-sectional view of the alternate embodiment of Fig. 10. Figure 1 clearly shows that this triangular gap spans the entire length of the seam 21 to the outside perimeter 26 of the covering material. Thus, the membrane of Zamierowski is not sealed to atmosphere in the region of the triangular gap. As a result, the internal chamber 46 communicates with atmospheric pressure. This air-gap structure disclosed in Zamierowski is consistent with the principle object of Zamierowski, which is not the treatment of a wound with reduced pressure, but is the evacuation of fluid from a wound.

Hence, the Zamierowski two-panel membrane 22 with its air gaps is not a "cover[/sheet]... adapted to maintain reduced pressure at the site of the wound" as variously recited in independent claims 9, 13, 14, 23, 27, 37, and 52. Neither is the two-panel membrane 22 of Zamierowski a "cover adapted for maintaining said reduced pressure at the wound" as recited in independent claims 19 and 34. Nor is the two-panel membrane 22 with its air gaps a

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“cover adapted to cover and enclose the wound and to provide a vacuum chamber about the wound to maintain reduced pressure at the site of the wound” as recited in independent claimed 24.

Further, Applicants respectfully submit that the two-panel membrane 22 of Zamierowski is not Applicants’ claimed “one-piece cover” as recited in independent claims 9 and 24, nor is it Applicants’ claimed “one-piece sheet” as recited in independent claim 23. Still further, Applicants respectfully submit the presence of the gaps at the juncture of the two panels 19 at the membrane perimeter 26 clearly indicates that Zamierowski does disclose the step of “sealing the periphery of said cover to tissue surrounding the wound to form a continuous seal” as recited in claim 30. (Emphasis Added.) Likewise, Zamierowski does not disclose the claimed structure of a “continuous, uninterrupted seal adapted to seal said cover to tissue surrounding the wound...” as recited in claim 13. (Emphasis Added.) The presence of gaps makes the Zamierowski perimeter bond non-continuous.

Turning now to the third indication, Zamierowski does not disclose a “reduced pressure supply means cooperating with said vacuum chamber to supply said reduced pressure of at least 0.11 atm beneath said vacuum chamber” as recited in independent claim 24. Rather, a principal function and purpose of the wound dressing of Zamierowski is to drain liquids from a wound. In furtherance of that goal Zamierowski discloses an active evacuation mode of operation as follows:

Alternatively, an active evacuation mode of operation involves attaching the tube 34 to the suction/vacuum source 42, whereby the fluid 20 is positively drawn from the wound site 12 and the chamber 46. (*Column 5, lines 44-48*)

Action of a suction/vacuum source does not necessarily mean that reduced pressure will be formed at the site of the wound. Indeed, Zamierowski never states that reduced pressure is formed at the site of the wound. With the cover of Zamierowski being open to atmosphere through the triangular air gaps, reduced pressure cannot be maintained within the wound chamber 12.

In addition to the above reasons for allowing each of the independent claims, yet further reasons exist. For example, Applicants respectfully submit that nowhere in Zamierowski is a

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“fluid trap” or “collection device” disclosed as variously recited in independent claims 9, 13, 14, 23, 27, 30, 33, 52. Likewise, Zamierowski does not disclose the step of “interposing a fluid trap between said suction port and said vacuum source” as recited in independent claims 19 and 34. Further, Zamierowski does not disclose the claimed structure of “a shut off for halting the application of reduced pressure when a predetermined amount of fluid is collected within said trap” as recited in independent claims 23 and 52.

Still further, Zamierowski, being a mere wound drainage device concerned with the removal of fluids, fails to disclose any method or structure for promoting the formulation of granulation tissue, which is important to wound healing. Thus, Zamierowski fails to disclose Applicants’ claimed step of “maintaining reduced pressure to promote the formation of granulation tissue at the wound until the wound has progressed toward a selected stage of healing” as recited in independent claim 19.

For the above reasons, Applicants respectfully submit that Zamierowski fails to disclose each and every element of the claimed invention, and therefore, respectfully request that the rejections of claims 9-14, 19, 23-26, 30-33, 37-41, 51, 52, 57-63, 72-75, and 83 be withdrawn.

REJECTIONS UNDER 35 U.S.C. 103(a)

Claims 15, 20-22, 27-29, 42-50, 53-56, 64-71, and 76-81 were rejected under 35 U.S.C. 103(a) as being unpatentable over Zamierowski. The office Action states that “[a]lthough to Zamierowski does not specifically disclose the tubular member embedded in the screen means this would have been an obvious modification in order to prevent the tube from moving out of the correct position or rotating such that the cover would block the port and thereby block the flow of suction. With respect to claims directed to specific ranges, it would have been obvious to one skilled in the art to discover the optimum workable ranges the device would operate at. With respect to claim 27, it further would have been obvious to provide filters to prevent any contamination of micro-organisms from the wound...”

Claims 15, 20-22, 64-71, and 76-81 have been canceled above rendering their rejection moot. Regarding claims 27-29, 42-50, and 53-56, Applicants respectfully submit that such

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claims are patentable for at least the reasons presents above with regard to the rejections under 35 U.S.C. 102. In addition, Applicants respectfully submit that the claimed recitation of specific [pressure] ranges cannot be obvious in view of a reference that fails to even disclose or suggest a device suitable for creating and maintaining reduced pressure at a wound site, as explained above. Specifically, Zamierowski does not disclose or suggest the creation of reduced pressure on an area of the skin including and surrounding the wound, because reduced pressure is not required for the evacuation of drained fluids. Moreover, Zamierowski **teaches away** from maintaining and creating reduced pressure when Zamierowski teaches that a relatively liquid-tight adhesive bond is **preferable**. (Zamierowski, column 4, lines 65-68). It can never be an obvious modification to do what a reference teaches away from. It cannot be an obvious modification of Zamierowski to attain specific values of reduced pressure, when Zamierowski never discloses or suggests that reduced pressure is desirable. With regard to the filter, Applicants respectfully request a reference in support of the Examiner's position.

For the above reasons, Applicants respectfully submit that claims 27-29, 42-50, and 53-56 are patentable over Zamierowski and therefore respectfully request withdrawal of the rejection of claims 27-29, 42-50, and 53-56.

In view of the foregoing amendments and remarks, it is believed that the claims in this application are now in condition for allowance. Early and favorable reconsideration is

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respectfully requested. The Examiner is invited to telephone the undersigned in the event that a telephone interview will advance prosecution of this application.

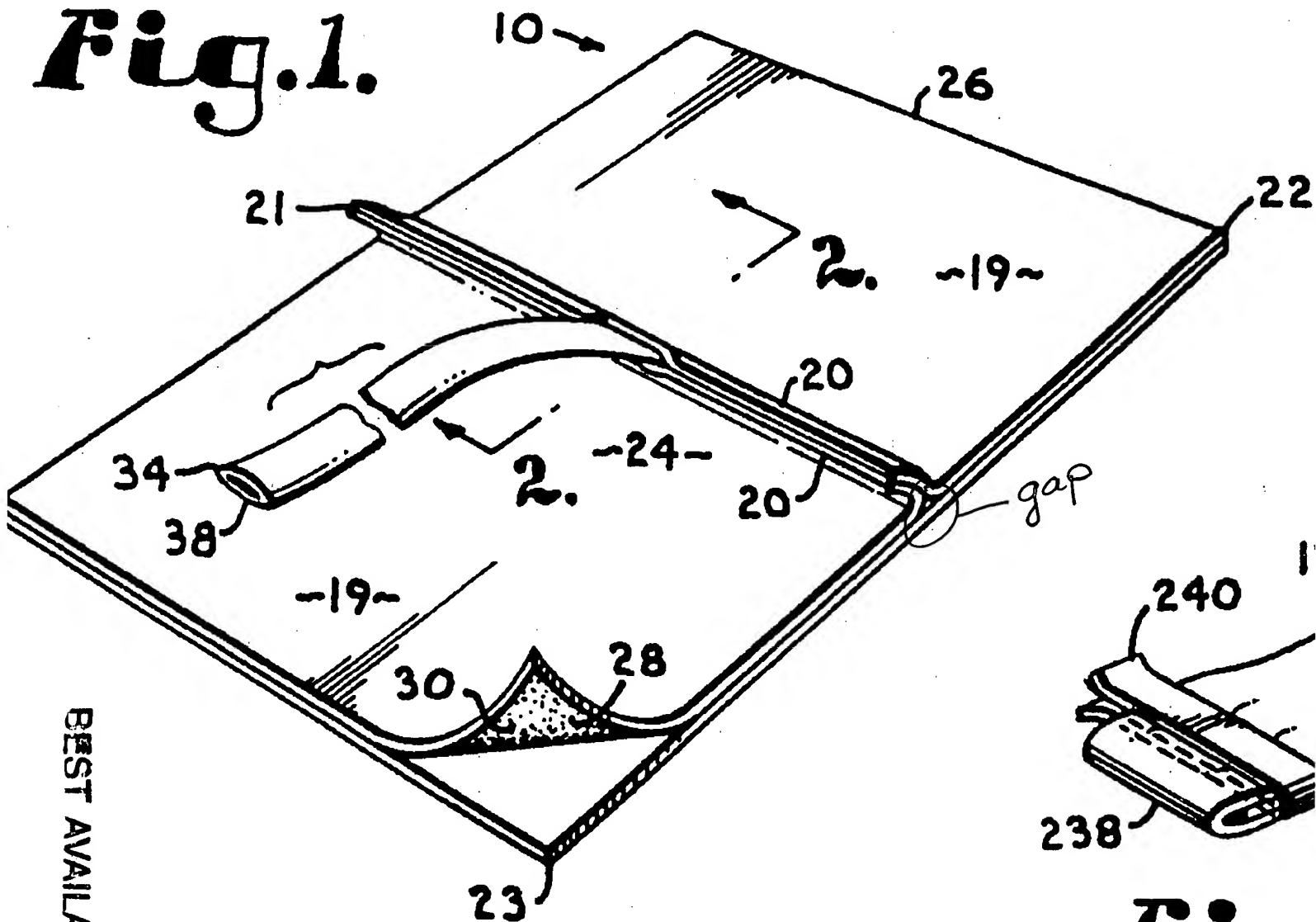
Respectfully submitted,



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Fig. 1.



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